



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0350]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Retailer Training Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0745. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Tobacco Retailer Training Programs

Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387u). FDA intends to issue regulations establishing standards for approved tobacco retailer training programs under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)). In the interim, FDA published a guidance document entitled “Tobacco Retailer Training Programs (Revised)” (2018) that can be downloaded at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-retailer-training-programs>. The guidance is intended to assist tobacco retailers to voluntarily implement effective training programs for employees.

The guidance discusses recommended elements that should be covered in a training program, such as: (1) Federal laws restricting the access to, and the advertising and promotion of, cigarettes, smokeless, and covered tobacco products; (2) the health and economic effects of tobacco use, especially when the tobacco use begins at a young age; (3) written company policies against sales to youth and other restrictions on the access to, and the advertising and promotion of, tobacco products; (4) identification of the tobacco products sold in the retail establishment that are subject to the Federal laws and regulations prohibiting their sale to underage persons; (5) age verification methods; (6) practical guidelines for refusing sales; and (7) testing to ensure that employees have the required knowledge. The guidance recommends that retailers require current and new employees to take a written test prior to selling tobacco products and that refresher training be provided at least annually and more frequently as needed. The guidance recommends that retailers maintain certain written records documenting that all individual employees have been trained and that retailers retain these records for 4 years in order to be able to provide evidence of a training program during the 48-month time period covered by the civil money penalty schedules outlined in the law.

The guidance also recommends that retailers implement certain hiring and management practices as part of an effective retailer training program. The guidance suggests that applicants

and current employees be notified both verbally and in writing of the importance of complying with laws prohibiting the sales of tobacco products to underage persons. In addition, FDA recommends that retailers implement an internal compliance check program and document the procedures and corrective actions for the program.

In the *Federal Register* of May 5, 2022 (87 FR 26766), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity; Guidance Section IV	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Develop training program	79,700	1	79,700	16	1,275,200
Develop written policy against sales to youth and employee acknowledgement	79,700	1	79,700	1	79,700
Develop internal compliance check program	79,700	1	79,700	8	637,600
Total					1,992,500

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden¹

Activity; Guidance Section IV	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Training program	79,700	4	318,800	0.25 (15 minutes)	79,700
Written policy against sales to youth and employee acknowledgement	79,700	4	318,800	0.10 (6 minutes)	31,880
Internal compliance check program	79,700	2	159,400	0.5 (30 minutes)	79,700
Total					191,280

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents in tables 1 and 2 is based on data from the deeming rule Final Regulatory Impact Analysis¹, which showed there are an estimated 362,273 retail establishments that currently sell tobacco products. The Agency reviewed these numbers again for this notice, and believe they are an accurate estimation. We assume that 75 percent of

¹ Deeming Tobacco Products to be Subject to the [Federal] Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act: Final Regulatory Impact Analysis, 2016 <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM500254.pdf>.

tobacco retailers already have some sort of age and identification verification training program in place. We expect that some of those retailer training programs already meet the elements in the guidance, some retailers would update their training program to meet the elements in the guidance, and other retailers would develop a training program for the first time. Thus, we estimate that two-thirds of tobacco retailers would develop a training program that meets the elements in the guidance (66 percent of 362,273 = 239,100; then annualized to 79,700).

We have adjusted our burden estimate and the number of respondents, which has resulted in a decrease to the currently approved burden and respondent count. This adjustment is based on available data estimating the number of retail establishments that sell tobacco products in the United States. Additionally, the burden chart was updated to reflect a change from an estimation over the course of 3 years to annualized burden.

Dated: November 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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